REMARKS

I. Amendments to the Claims

The Office objected to previous claim 20 for allegedly being an improper process claim. Claim 20 has been rewritten as a method claim and presumably now falls in Group II. Claim 2 has been amended to correct a typographical error. Claim 10 has been amended to improve grammar. No new matter has been added by way of these amendments.

II. Election of Claims

The Office requires Applicants to elect claims from one of the following groups for further prosecution:

> Group I, claims 1-13 and 19, drawn to carriers for diagnosis of a Treponema infection, the carriers comprising at least one immobilized cardiolipin and at least one immobilized Treponema-specific antigen; and
>
> Group II, claims 14-18, directed to methods for diagnosing a Treponema infection comprising contacting a patient's sample with the inventive carrier.

The Examiner also indicated that the claims of Group 1 are directed to patentably distinct antigens, and directed Applicants to elect a single antigen or combination of antigens recited in claim 5 for further examination. The Office instructs that the examination will be restricted to only the elected antigen, and the restriction should not be construed as an election of species. Clarification of all of the distinct inventions for the record is requested, to avoid ambiguity as to proper divisionals in the future.

Applicants elect, with traverse, Group I, claims 1-13 and 19, directed to carriers for diagnosis of a Treponema infection. With respect to Group I, Applicants further elect the 47 kD antigen of claim 5 for examination.

III. The Restriction Requirement Is Improper

Applicants request reconsideration of the restriction requirement. The Office contends that the claims of Groups I and II do not relate to a single general inventive concept because they allegedly lack the same or corresponding special technical features. The Office

asserts that the technical feature uniting the claims is a carrier comprising at least one immobilized cardiolipin and at least one immobilized Treponema-specific antigen, but contends that it would be obvious to combine the cardiolipin antigen and the 47 kDa Treponema-specific antigen in a single carrier in view of West et al., *Sex. Transm. Infect.*, 78:282-285 (2002) ("West"). Thus, according to the Office, the common technical feature of the claims of Group I and II does not define a contribution over the art.

Contrary to the Office's assertion, the common technical feature uniting the pending claims is not obvious in view of the cited art. The rapid plasma regain (RPR) test of West does not comprise immobilized cardiolipin (see, e.g., page 282, col. 2, paragraph 1). Previous RPR tests, such as that described in West, provides a non-immobilized VDRL antigen (i.e., cardiolipin in liquid form). Unlike the claimed invention, these previous RPR tests require dilution of a sample prior to application to a carrier. Furthermore, West teaches performing RPR tests and rapid syphilis tests (RSTs) separately, requiring two different systems with differing reagent stability and different reliability in clinic conditions.

In contrast, the materials and methods of the invention entail immobilized lipids (e.g., cardiolipin, lecithin, and cholesterol) on a solid carrier, which ensures antibody reactivity. Furthermore, the invention allows two reactions to be performed simultaneously. West does not teach or suggest a system wherein multiple reagents are immobilized on a single carrier to allow integrated one step analysis. Thus, the technical feature uniting the pending claims, i.e., immobilization of at least one cardiolipin *and* at least one Treponema-specific antigen on a carrier, is novel and unobvious in view the art, and represents a general inventive concept under PCT 13.1.

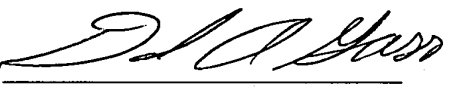
The restriction of examination to the 47 kDa antigen of claim should be withdrawn, as the antigen used in the inventive materials and methods entails the same, uniting patentable feature described above. In addition, the restriction is improper because it does not meet the standard set forth in M.P.E.P. § 803. For a proper restriction requirement, M.P.E.P §803 indicates that the Examiner must show: (1) the inventions are independent or distinct and (2) there would be a serious burden on the Examiner if the restriction is not required. Referring to the second requirement, § 803 recites that "if the search or examination of an entire application can be made without serious burden, the Examiner must

examine it on the merits, even though it includes claims to independent or distinct inventions." The Examiner failed to satisfy the second prong of this test in failing to establish that search and examination of the antigens of the Markush group of claim 5 would be any burden, much less a serious burden, on the Examiner.

Applicants submit that the application is in condition for allowance and respectfully request notification of the same.

Dated: October 4, 2007

Respectfully submitted,

By 

David A. Gass
Registration No.: 38,153
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant